

P&E Draft for 10173-073-999 - Monday, August 4, 2003

### REMARKS

The Applicants thank the Examiner with much appreciation for his indication that claims 17-29 would be allowable if a terminal disclaimer is filed and if the limitation that the liposomes are "empty liposomes" and the limitation the mean diameters recited have the Gaussian distribution profile are recited in claim 17. In accordance with the Examiner's suggestion, the Applicants have amended claim 17 to indicate that the liposomes are "empty" (i.e., contain no encapsulated drug). In addition, the Applicants submit herewith a terminal disclaimer disclaiming the terminal part of any patent granted on the above identified application which would extend beyond the expiration date of U.S. Patent Nos. 6,312,719 and 5,746,223.

Claims 30-43 have been canceled without prejudice. The cancellation of claims 30-43 were made herein for the purpose of pursuing such canceled subject matter in related applications at the option of the Applicants and not for patentability. Thus, the Applicants expressly reserve the right to prosecute any unclaimed or canceled subject matter in the present application or in any related application.

Claims 17-29 have been amended. Claim 17 has been amended to indicate that the liposomes are "empty," claim 18 has been amended to be independent, and claims 19-29 have been amended to indicate the proper dependency of each claim. The amended claims are fully supported by the specification and claims as originally filed and do not constitute new matter. Specifically, the limitation of "empty" liposomes in the claims is supported by the specification at p. 24, ll. 12-18 (disclosing liposome [200] comprised of a phospholipid bilayer where the polar head groups [500] of the outer leaflet face outward to the surrounding aqueous environment and the polar head groups [500] of the inner leaflet face inward to the aqueous (empty) core [202] of liposome particle [200]) and p. 20, l. 3 (indicating that the liposomes are not bound to or are otherwise free of drug).

This Reply Under 37 C.F.R. §1.111 With Amendment is being submitted within 2 months of the mailing date of the current final office action. Thus, Applicants note that if an advisory action is not mailed until after the end of the three month shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and extension fee will be calculated from the mailing date of the advisory action.

1. **The Obviousness-Type Double Patenting Rejection Should Be Withdrawn**

The rejection under the judicially created doctrine of obvious-type double patenting should be withdrawn since the rejection is moot in view of the terminal disclaimer the Applicants have submitted herewith disclaiming the terminal part of any patent granted

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on the above identified application which would extend beyond the expiration date of U.S. Patent Nos. 6,312,719 and 5,746,223.

2. **The Rejection Under 35 U.S.C. §112  
Second Paragraph, Should Be Withdrawn**

The Examiner rejects claims 17-33 under 35 U.S.C. § 112, second paragraph, as being indefinite because according to the Examiner, if the majority of liposomes (68%) have sizes 100-150 nm in claim 18, it is unclear how one can recite liposomes with sizes of 95-155 nm with the standard deviation recited in parent claim 17. This rejection is moot since claim 18, as amended, is now an independent claim. Accordingly, the rejection under 35 U.S.C. §112, second paragraph, should be withdrawn.

3. **The Rejections Under 35 U.S.C. § 102 & 103 Should Be  
Withdrawn**

As stated above the Examiner has indicated that claims 17-29 would be allowable if a terminal disclaimer is filed and if the limitation that the liposomes are "empty liposomes" and the limitation the mean diameters recited have the Gaussian distribution profile are recited in claim 17. The Applicants have amended the claims and filed a terminal disclaimer in accordance with the Examiner's instructions to put the application into condition for allowance. Accordingly, the rejections under 35 USC 102 and 103(a) are moot in view of the Applicant's amendments and should be withdrawn.

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**CONCLUSION**

Entry of the foregoing amendments and remarks is respectfully requested. No fee is believed to be due with this Reply other than the fee for a Petition for Extension of Time. However, if any other fee is required, please charge the fee to Pennie & Edmonds LLP Deposit Account No. 16-1150. In view of the above remarks and amendments, it is submitted that the presently pending claims are in form for allowance and early action to that end is requested. If any issues remain, the Examiner is requested to telephone the undersigned at (212) 790-9090.

Respectfully submitted,

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